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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,425	11/15/2000	Leonard Presta	P1726R1P1	3384

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/713,425

Applicant(s)

PRESTA, LEONARD

Examiner

David A. Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-63 and 80-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-63 and 80-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Amendment of 12/2/05 has been entered. Claims 60-63 and 80-82 are pending and under examination.

The amendment has overcome previously stated issues as follows:

The objection to claim 63 under 37 CFR 1.75. The examiner concurs that claim 63 is not a duplicate of claim 80.

The rejection of claims 60-63 and 80-82 under 35 USC 101 and 35 USC 112, 1st paragraph for lack of utility and failure to teach how to use. The examiner considers that the disclosure of a step of “determining binding of the variant Fc region to an FcR” (e.g. page 10, lines 28 and 33) would clearly apprise one of skill that the instantly claimed complexes would be formed in binding assays of various formats.

The prior art rejections based upon Idosogie et al (WO 99/51642, US ‘195 and US ‘624).

The following rejections of record are maintained or modified as follows:

Claims 60-63 and 80-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter.

Claims 60-63 and 80-82 contain new matter because they encompass merely the free complex of a polypeptide having a variant Fc region and the Fc.gamma.R. Applicant has urged that there are low affinity binding assays disclosed at pages 98-99 and 106 in which a variant Fc containing polypeptide, in monomeric form, becomes bound to an Fc.gamma.R allotype. The examiner finds that, in each of these assays, there is a formation of more than the simple complex of a polypeptide having a variant Fc region and the Fc.gamma.R. That is, in each case the Fc.gamma.R is either bound to a solid phase or to a cell surface (note also teachings at page 39, lines 6 and 14-180. While applicant may have disclosed the concept of binding assays involving a polypeptide having a variant Fc region and the Fc.gamma.R in a general sense (e.g. page 10, lines 28 and 33), applicant did not provide teachings of the various formats in which such an assay might be conducted, except at pages 38-40, 98-99 and 106-107, wherein all assays,

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whether involving high affinity or low affinity binding, were conducted with the Fc.gamma.R on a solid phase/support or a cell surface. Applicant is thus claiming more than was expressly disclosed.

Applicant's arguments filed 12/2/05 have been fully considered but they are not persuasive. While the arguments are persuasive regarding utility/how to use, they are not with respect to written description/new matter. The former issue can be overcome by a teaching of one embodiment and/or what one of skill might appreciate from the disclosure. For the latter, however, there is a higher standard; applicant must have clearly described the claimed invention for its full scope and not rely upon what would have been obvious to one of skill. *Lockwood v. American Airlines* 41 USPQ2d 1961.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 2/17/06 DAS


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644